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GE Medical Systems
P.O. Box 414, W-709
Milwaukee, WI 53201 USA

K012389

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

Identification of Submitter: Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
GE Medical Systems
Tel. (262) 544-3894
Summary prepared: 25 June 2001

Identification of Product: Revolution XR/d Digital Radiographic Imaging System
Classification Name: Stationary X-ray System
Manufacturer: GE Medical Systems
3000 N. Grandview Blvd.
Waukesha, WI 53188

Device Description: The Revolution XR/d Digital Radiographic Imaging System is designed to perform radiographic x-ray examinations. The detector is comprised of amorphous silicon with a cesium iodide scintillator. The resulting digital image can be sent through a DICOM network for applications such as printing, viewing, and storage. The Revolution XR/d Digital Radiographic Imaging System consists of an elevating radiographic table with integrated digital detector, x-ray tube, x-ray tube hanger, collimator, system controller, generator, and tilting radiographic wall stand with integrated digital detector. The configuration can consist of digital table and digital wall stand, digital table only, or digital wall stand only.

Indications for Use: The Revolution XR/d Digital Radiographic Imaging System is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures. This device is not intended for mammographic applications.

Comparison with: The Revolution XR/d Digital Radiographic Imaging System is an enhanced version of and substantially equivalent to the

Revolution XR/D Digital Radiographic Imaging System, originally cleared in K992066.

Conformance:

The Revolution XR/d Digital Radiographic Imaging System will conform to applicable sections of 21CFR 1020.30, 1020.31, and 1020.32. The system will also conform to UL 2601-1, IEC 601-1, IEC 601-1-2, and IEC 601-1-3.

Conclusions:

In the opinion of GE Medical Systems, the Revolution XR/d Digital Radiographic Imaging System is substantially equivalent to the presently marketed Revolution XR/D Digital Radiographic Imaging System (K992066). The Revolution XR/d Digital Radiographic Imaging System does not include any new indications for use, nor does use of this device result in any new potential hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

General Electric Medical Systems
% Mr. Reiner Krumme
Manager, Medical Division
TUV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

AUG 21 2013

Re: K012389
Trade/Device Name: Revolution XR/D Digital Radiographic Imaging System
(Radiographic x-ray system with SSXI)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: July 23, 2001
Received: July 27, 2001

Dear Mr. Krumme:

This letter corrects our substantially equivalent letter of August 10, 2001.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(k) Number (if known): K012389

Device Name: Revolution XR/d Digital Radiographic X-ray System

Indications for Use

The Revolution XR/d Digital Radiographic X-ray System is indicated for use in generating radiographic images of human anatomy. It is intended for use in replace radiographic film/screen systems in all general purpose diagnostic procedures. This device is not intended for mammographic applications.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801-109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012389